



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

COPY MAILED

SEP 28 2009

OFFICE OF PETITIONS

Wellstat Management Company, LLC
LEGAL DEPARTMENT
930 CLOPPER ROAD
GAITHERSBURG MD 20878

In re Patent No. 7,514,555	:
Hodge et al.	:
Application No. 10/531618	: DECISION ON
Issue Date: 04/07/2009	: REQUEST FOR RECONSIDERATION
Filing or 371(c) Date: 04/14/2005	: OF PATENT TERM ADJUSTMENT
Attorney Docket No. 18034-PCTUS	:

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(d)," filed June 3, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from 82 days, to not less than 241 days. The application is properly treated under 37 CFR §1.705(d).

The request for reconsideration of patent term adjustment is **DISMISSED**.

On April 7, 2009, the above-identified application matured into US Patent No. 7,514,555 with a patent term adjustment of 82 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, the term of the patent is extended for the number of days that issuance of the patent was delayed by failures of the Office to promptly take certain actions (35 U.S.C. § 154(b)(1)(A) ("A delays"), and the term of the patent is extended for the number of days that the Office failed to issue a patent by the three-year anniversary of the date that the application for patent was first filed (35 U.S.C. § 154(b)(1)(B) ("B delays"). Patentees state that the Patent Term Adjustment is calculated by adding the "A delays" plus the "B delay," except to the extent that the periods of delay overlap 35 U.S.C. § 154(b)(2)(A)). Application for PTA at p.2. Patentees maintain that there is no overlap between the "A delays" and the "B delay" in this case. Therefore, Patentees

that the period of adjustment is 517 days, which is the sum of 159 days of “A delays” and 358 days of “B delay.

The 358-day period is calculated based on the date the application commenced the national stage on April 14, 2005, and the patent having been issued on April 7, 2009, three years and 358 days later. Patentees assert that in addition to this 358-day period, they are entitled to a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) totalling 159 days. This 159-day period is the result of a period of delay of 146 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which application was filed under 35 U.S.C. 111(a), pursuant to 37 CFR 1.702(a)(1), and a period of delay of 13 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed, pursuant to 37 CFR 1.702(a)(2).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The Office agrees that as of the issuance of the patent on April 7, 2009, the application was pending three years and 358 days after its filing date. The Office agrees that the action detailed above was not taken within the specified time frame, and thus, the entry of a period of adjustment of 159 days is correct. At issue is whether patentees should accrue 358 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 159 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 159 days of examination delay overlap with the 358 days of delay in issuance of the patent. Patentees’ calculation of the period of overlap is inconsistent with the Office’s interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to

interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the date the application commenced the national stage.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, April 14, 2005, to the date the patent issued on April 7, 2009. Prior to the issuance of the patent, 159 days of patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application. All of the 159 days of Office delay overlap with the 358 days for Office delay in issuing the patent. During that time, the issuance of the patent was delayed by 358 days, not 159 days + 358 days. The Office took 14 months and 143 days to issue a first Office action, and four months and 13 days to respond to a reply under 35 U.S.C. 132. Otherwise, the Office took all actions set forth in 37 CFR 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 159 days of Office delay and the time allowed within the time frames for processing and examination, the application issued three years and 358 days after its filing date. The Office did not delay 159 days and then an additional 358 days. Accordingly, 358 days of patent term adjustment was properly entered because the period of delay of 159 days attributable to grounds specified in § 1.702(a) overlaps with the adjustment of 358 days attributable to the delay in the issuance of the patent. Entry of both periods is not warranted.

Accordingly, at issuance, the Office entered 358 days of patent term adjustment.

In view thereof, no adjustment to the patent term will be made.

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Attorney Derek Woods, at (571) 272-3232.

A handwritten signature in black ink, appearing to read 'Alesia Brown', with a stylized flourish extending to the right.

Alesia Brown
Senior Petitions Attorney
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy